



# Guilty Even After Proven Innocent: The Vaccine-Autism Myth and its Consequences

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# Guilty Even After Proven Innocent

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The Vaccine-Autism Myth and its Consequences

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**Class of 2011**

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## **Abstract**

In 1998, Dr. Andrew Wakefield began promoting the idea that the MMR vaccine could be linked to autism. The media soon picked up on Wakefield's idea, propagating a myth about vaccines and autism with celebrity assistance and the support of certain government officials. As a result, vaccination rates dropped, outbreaks of diseases normally prevented by vaccination occurred, and segments of the population developed long-term concerns about vaccine safety. All this happened in spite of multiple studies and reports from researchers and prominent health agencies denying a causal connection between autism and vaccines as well as an in-depth investigation that ultimately found Wakefield's work to be the product of severe ethical violations. That the myth has persisted in the face of such damning evidence to the contrary demonstrates the power of the Internet and its wealth of (mis)information, a development with which public health agencies and the medical community must come to terms if they are to combat the vaccine-autism myth effectively. The medical community must also begin to engage in more dialogue with parents so that doctors can demonstrate to parents why their expertise should be trusted over the myriad of information available online. By rebuilding parental trust in the medical profession as opposed to the Internet, the vaccine-autism myth may finally be rejected so that children will be protected from disease and attention can turn to the pressing issue of what actually causes autism. This result would be the most beneficial outcome for children, a goal that all parties to the controversy can support.

## Introduction: A Brief History of Vaccinations

Throughout history, diseases have wreaked havoc on the human population. For example, smallpox, a once-dreaded virus, has been traced back to at least the second century AD.<sup>1</sup> In the 1500s, when Europeans and their illnesses first began appearing on the shores of the New World, smallpox devastated indigenous populations, killing one-third of the natives in a remarkably short period of time.<sup>2</sup> And although Europeans had a higher level of immunity to smallpox due to prolonged exposure, they were not entirely protected: in the 18th century, approximately 400,000 Europeans died annually from the virus.<sup>3</sup> While terrifying, smallpox was not the only disease capable of such deadly outcomes at the time.<sup>4</sup>

Given the devastation caused by smallpox and many other contagious diseases, their virtual disappearance from much of the industrialized world is a cause for celebration. And the guest of honor at such a celebration would be the vaccine. Indeed, the Centers for Disease Control and Prevention (“CDC”) has compiled a list of the greatest public health achievements of the 20th century, with vaccinations taking first place on the list.<sup>5</sup> The first vaccine was developed in the late 18th century by Edward Jenner, an English country doctor. He observed that milkmaids who were infected with cowpox were subsequently immune from smallpox. Based on this observation, Jenner inoculated a boy with pus from a cowpox lesion and then repeatedly exposed the child to smallpox. When this and other similar experiments demonstrated

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<sup>1</sup> John M. Eyler, *Smallpox in History: The Birth, Death, and Impact of a Dread Disease*, 142 J. OF LABORATORY & CLINICAL MED. 216, 216 (2003).

<sup>2</sup> WILLIAM H. MCNEILL, PLAGUES AND PEOPLES 217 (1998).

<sup>3</sup> Eyler, *supra* note 1, at 216.

<sup>4</sup> Measles, typhus, influenza, diphtheria, and mumps are examples of other potentially deadly diseases in existence by the 1500s. MCNEILL, *supra* note 2, at 217-18. Even into the late 19th century, some of these maladies were responsible for killing one in five children in the United States before he or she reached the age of five. Alexandra Minna Stern & Howard Markel, *The History of Vaccines and Immunization: Familiar Patterns, New Challenges*, 24 HEALTH AFF. 611, 611 (2005).

<sup>5</sup> CDC, *Ten Great Public Health Achievements -- United States, 1900-1999*, 48 MORBIDITY AND MORTALITY WKLY REP. 241 (1999), available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/00056796.htm>.

that the inoculated subjects did not develop smallpox, Jenner published his findings in a book in 1798 entitled *Inquiry into the Causes and Effects of the Variolae Vaccine*.<sup>6</sup> Although some immediately praised Jenner's work and saw it as the herald of the end of smallpox,<sup>7</sup> actual eradication of the disease did not occur until almost two centuries later.

European countries first began promoting smallpox vaccination in the early 19th century, moving to increasingly forceful methods in order to obtain compliance from citizens.<sup>8</sup> For example, England passed several Vaccinations Acts in the mid-19th century. The first Act, passed in 1840, provided free vaccination to the poor. By 1853, compulsory vaccination of infants under three months of age had been established in the country.<sup>9</sup> Along with mandatory vaccination, England undertook to improve the infrastructure supporting vaccination, by issuing new rules aimed at improving the quality of the vaccine itself as well as the skill of those who conducted vaccinations.<sup>10</sup> Following these improvements, England passed another Vaccination Act in 1867, making vaccinations mandatory for all children under fourteen years of age. Parents who did not get their children vaccinated could be fined repeatedly until they complied with the law.<sup>11</sup>

The United States was similarly interested in Jenner's discovery. In 1800, Dr. Benjamin Waterhouse of Harvard Medical School conducted his own experiments and verified Jenner's findings.<sup>12</sup> Physicians soon began offering vaccinations. However, smallpox vaccination ran into several difficulties in the United States, the most significant one having to do with obtaining a

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<sup>6</sup> Stern & Markel, *supra* note 4, at 612.

<sup>7</sup> Eyler, *supra* note 1, at 218 (quoting a letter from Thomas Jefferson to Jenner praising the latter for his discovery).

<sup>8</sup> *Id.*

<sup>9</sup> Dorothy Porter & Roy Porter, *The Politics of Prevention: Anti-Vaccinationism and Public Health in Nineteenth-Century England*, 32 MED. HIST. 231, 231-33 (1988).

<sup>10</sup> *See id.* at 233.

<sup>11</sup> *Id.*

<sup>12</sup> Rohit K. Singla, *Missed Opportunities: The Vaccine Act of 1813*, in Chapter I(A) of the Electronic Book 19 (1998).

pure source of the vaccine.<sup>13</sup> At the time, there was no known method to produce the vaccine artificially. Instead, physicians relied on arm-to-arm transmissions, harvesting live cowpox virus from the infected pustule of a vaccinated person and using it to vaccinate other individuals.<sup>14</sup> One of the major problems with carrying out vaccinations in this manner was that other diseases could also be spread from one person to the next.<sup>15</sup> In response, Congress enacted the Vaccine Act of 1813 to secure a genuine national source for the smallpox vaccine.<sup>16</sup> While the Act was repealed in 1822, the repeal may have had more to do with politics rather than animus towards vaccination.<sup>17</sup>

England's Vaccination Acts experienced opposition as well. Not everyone believed in the efficacy of vaccination; even members of the medical community were against the procedure.<sup>18</sup> Vaccination was also objected to for religious reasons because it was seen as an improper interference with Divine Providence.<sup>19</sup> Once vaccinations became compulsory, a National Anti-Compulsory Vaccination League was formed to seek repeal of the vaccination acts.<sup>20</sup> The League was not entirely successful, but managed to obtain a conscience clause in the Vaccination Act of 1989, which excused parents who genuinely believed vaccines to be ineffective and who did not want infectious materials to be introduced into their children from being fined for disobeying the law.<sup>21</sup> A similar conscientious objection provision has survived

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<sup>13</sup> *Id.* at 24.

<sup>14</sup> *Id.* at 27.

<sup>15</sup> *Id.* at 28 (“The accidental transmission of syphilis was particularly common”); Porter & Porter, *supra* note 9, at 233-34 (two accounts of syphilis being transmitted through arm-to-arm vaccination in England gave rise to concerns about other diseases being spread in the same way).

<sup>16</sup> Singla, *supra* note 12, at 40.

<sup>17</sup> Singla posits that the repeal of the Act was mainly “a politically expedient response” to a mistake in which the National Vaccine Agent responsible for providing pure vaccines accidentally sent a doctor in North Carolina samples of smallpox to use in vaccinating people, resulting in a smallpox outbreak that killed several people. *Id.* at 66-67.

<sup>18</sup> Porter & Porter, *supra* note 9, at 236-37.

<sup>19</sup> *Id.*

<sup>20</sup> Eyler, *supra* note 1, at 219.

<sup>21</sup> Porter & Porter, *supra* note 9, at 234, 251.

into the modern day and is being used by parents in the wake of the vaccine-autism controversy to excuse their children from receiving certain vaccines.

Despite the setbacks and opposition to smallpox vaccination, the process continued throughout the 19th and 20th centuries, leading to a decrease in outbreaks in the developed world. By the end of World War II, western countries had all but gotten rid of the virus within their borders and the focus shifted to the developing world.<sup>22</sup> In 1958, the World Health Organization (“WHO”) first announced the goal of eradicating smallpox from the world. But it was not until 1967 that the WHO seriously devoted its resources to this goal. Using a strategy of surveillance, isolation, and vaccination, the WHO finally achieved eradication in 1979.<sup>23</sup> Thanks to these national and international efforts, routine vaccination for smallpox is no longer necessary and the biggest concern about smallpox in modern times is that it might be used as a biological weapon, not that natural outbreaks will occur to claim lives.<sup>24</sup>

After Jenner developed the smallpox vaccine, other discoveries followed. Louis Pasteur created vaccines against anthrax, cholera, and virus-caused rabies in the late 19th century. Later on, vaccines for a variety of other diseases, including typhoid fever, tetanus, and diphtheria, were discovered.<sup>25</sup> Now, the CDC recommends a number of vaccines for children to receive, ranging from Hepatitis A and B to Varicella (commonly known as chickenpox).<sup>26</sup> Furthermore, states

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<sup>22</sup> Eyler, *supra* note 1, at 219.

<sup>23</sup> *Id.* at 219-20.

<sup>24</sup> PETER BARTON HUTT ET AL., FOOD AND DRUG LAW: CASES AND MATERIALS 896 (3rd ed. 2007) (noting that government officials are currently dealing with the threat of purposeful exposure of the population to smallpox as an infectious agent); Janie Parrino & Barney S. Graham, *Smallpox Vaccines: Past, Present, and Future*, 118 J. ALLERGY & CLINICAL IMMUNOLOGY 1320, 1320 (2006).

<sup>25</sup> Maurice R. Hilleman, *Vaccines in Historic Evolution and Perspective: A Narrative of Vaccine Discoveries*, 18 VACCINE 1436, 1438 (2000).

<sup>26</sup> CDC, 2010 RECOMMENDED IMMUNIZATIONS FOR CHILDREN FROM BIRTH THROUGH 6 YEARS OLD (2010), available at <http://www.cdc.gov/vaccines/events/niiw/2010/downloads/educ/parent-ver-sch-0-6yrs-508.pdf>.

have certain required vaccinations for children entering daycare or the school system.<sup>27</sup> The public's participation in vaccination has helped dramatically to increase the survival rate for newborns and young children.<sup>28</sup> The medical community has also largely embraced vaccines and the hope of disease prevention that they offer, seeking solutions for the troubling diseases of the modern era such as tuberculosis, Hepatitis C, and HIV/AIDS.<sup>29</sup>

With all the benefits to be derived from vaccinations, a troubling development occurred in the late 1990s, which has had long-lasting repercussions. As noted, since the 1800s there have been members of the public who have expressed resistance to vaccination. Dr. Andrew Wakefield's actions fueled that resistance in the modern era, giving it new life. In 1998, Dr. Wakefield, along with several other researchers, published a five-page paper in *The Lancet*, a well-known British medical journal, entitled *Ileal-Lymphoid-Nodular Hyperplasia, Non-Specific Colitis, and Pervasive Developmental Disorder in Children*. While the name of the article may not have been particularly memorable, its consequences certainly were. According to Wakefield et al., development of behavioral disorders, namely autism, and intestinal abnormalities could be linked to the Measles, Mumps, and Rubella ("MMR") vaccine.<sup>30</sup> Although other researchers quickly responded with their own studies challenging Wakefield's findings, the damage was done. The idea that vaccines caused autism entered the public discourse, creating fear and anger that lingered long after Wakefield's research had been rejected by the medical community. This paper seeks to explore the history and evolution of the vaccine-autism myth as well as its long-term social consequences.

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<sup>27</sup> CDC, *Vaccines: Requirements and Laws* (May 3, 2010), <http://www.cdc.gov/vaccines/vac-gen/laws/default.htm#school>.

<sup>28</sup> See *supra* note 4.

<sup>29</sup> Hilleman, *supra* note 25, at 1445.

<sup>30</sup> A. J. Wakefield et al., *Ileal-Lymphoid-Nodular Hyperplasia, Non-Specific Colitis, and Pervasive Developmental Disorder in Children*, 351 LANCET 637, 637 (1998).



Part One of the paper will discuss Wakefield and his research. Parts Two and Three will focus on the responses of the medical community and of the public with regard to the supposed connection between autism and vaccination. Part Four will deal with recent developments concerning Wakefield and his questionable research. Part Five will delve into the aftermath of the vaccine-autism myth and Part Six will cover the lessons to be learned from the controversy as well as possible future courses of action to undo the damage of the myth.

## **I. The Man and the Myth**

Andrew Wakefield, lead author of the 1998 article suggesting a link between autism and the MMR vaccine, is not a charlatan peddling magical cure-alls to an unsuspecting public; he has the credentials of a serious medical researcher. Born in England to a physician mother and a neurologist father, he studied medicine at St. Mary's Hospital, ultimately choosing a career in gastrointestinal surgery.<sup>31</sup> He won a fellowship to study in Canada for a period of time before returning to the United Kingdom in the late 1980s, where he ended up working at the Royal Free Hospital in London.<sup>32</sup> At the age of thirty-two, he found the answer to what causes Crohn's disease, something other researchers had been working on for decades.<sup>33</sup> Clearly, Wakefield was a capable researcher. And in that capacity, he began looking into autism and the MMR vaccine in 1996.<sup>34</sup> Two years later, he published his findings.

Wakefield's research centers on twelve children between the ages of three and ten who initially had normal development but subsequently lost some acquired skills while gaining

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<sup>31</sup> Rebecca Smith, *Andrew Wakefield - The Man Behind the MMR Controversy*, TELEGRAPH (London), Jan. 29, 2010, [http://www.telegraph.co.uk/health/healthnews/7091767/Andrew-Wakefield-the-man-behind-the-MMR-controversy.html?sms\\_ss=email&at\\_xt=4d50aab6825e9169%2C0](http://www.telegraph.co.uk/health/healthnews/7091767/Andrew-Wakefield-the-man-behind-the-MMR-controversy.html?sms_ss=email&at_xt=4d50aab6825e9169%2C0).

<sup>32</sup> *Id.*

<sup>33</sup> PAUL A. OFFIT, *AUTISM'S FALSE PROPHETS: BAD SCIENCE, RISKY MEDICINE, AND THE SEARCH FOR A CURE* 18 (2008).

<sup>34</sup> Smith, *supra* note 31.

gastrointestinal problems.<sup>35</sup> After describing the various diagnostic tests that were run on the children, Wakefield notes in the Results section of the paper that in eight of the children, the onset of problems had been linked by their parents to the MMR vaccine.<sup>36</sup> In these children, the average time between receiving the vaccine and developing behavioral symptoms was 6.3 days.<sup>37</sup> For example, one child received a dose of the MMR vaccine when he was four-and-a-half years old. One day later, his mother noticed a “striking deterioration in his behavior[,]” which she linked to the vaccine.<sup>38</sup> The paper then moves into the Discussions section, where Wakefield et al. discuss possible causes of autism. Noting a connection between intestinal dysfunction and autism, Wakefield first mentions the “opioid excess” theory of autism, which links autism to digestive problems.<sup>39</sup> If the MMR vaccine causes these digestive problems, it would be a possible cause of autism as well. Following the discussion of the “opioid excess” theory, Wakefield et al. state that the MMR vaccine has been implicated as a possible cause of autism, though they clarify in a later paragraph that they have not actually proven such an association between the two.<sup>40</sup>

The 1998 paper did not definitively point to the MMR vaccine as the cause of autism and neither was Wakefield the first researcher to note a link between autism and vaccination. Another paper had been published two years earlier in which Dr. H. H. Fudenberg notes that autism may be due to adverse reactions to a live virus vaccine, although he limits the statement to those with a genetic predisposition to the disorder.<sup>41</sup> Taken on its own, then, Wakefield’s paper was not earth-shattering and did not make any strong statements about the MMR vaccine

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<sup>35</sup> Wakefield et al., *supra* note 30, at 637.

<sup>36</sup> *Id.* at 638.

<sup>37</sup> *Id.*

<sup>38</sup> *Id.*

<sup>39</sup> *Id.* at 640.

<sup>40</sup> *Id.* at 640-41.

<sup>41</sup> H. H. Fudenberg, *Dialysable Lymphocyte Extract (DLyE) in Infantile Onset Autism: A Pilot Study*, 9 *BIOETHERAPY* 143, 146 (1996).

and autism. However, Wakefield went one step further, participating in a press conference where he stated that he could no longer support the use of the MMR vaccine because he considered such use to be a “moral issue” in need of urgent investigation.<sup>42</sup> As Wakefield explained at the press conference, he believed the MMR vaccine led to autism by causing infection and inflammation of the intestine upon injection. Once the intestine was damaged, harmful proteins could pass through it and into the bloodstream, ultimately finding their way to the brain and damaging it.<sup>43</sup> And thus a myth was born.

## **II. The Medical Community’s Response**

The medical community responded quickly to Wakefield’s paper and his public comments. It is not possible to give a detailed account of every report that came out in the subsequent months and years refuting Wakefield et al.’s findings so only a sampling is given in the following pages.

### **A. Chen & DeStefano’s Contemporaneous Warning**

In the same issue of *The Lancet* where Wakefield et al. published their paper, Robert T. Chen and Frank DeStefano of the Vaccine Safety and Development Activity National Immunization Program (part of the CDC) submitted a brief piece of commentary urging caution in accepting Wakefield’s suggestion of a link between the MMR vaccine and autism.<sup>44</sup> Chen and DeStefano begin by pointing out that millions of people have been receiving the MMR vaccine since the 1960s without developing either bowel or behavioral problems, which demonstrates at the very least that even if the vaccine causes autism, it is an exceedingly rare occurrence.<sup>45</sup>

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<sup>42</sup> Nick Triggle, *Wakefield and Autism: The Story that Will Not Go Away*, BBC NEWS, Jan. 28, 2010, <http://news.bbc.co.uk/2/hi/health/8481583.stm>.

<sup>43</sup> OFFIT, *supra* note 33, at 20-21.

<sup>44</sup> Robert T. Chen & Frank DeStefano, Commentary, *Vaccine Adverse Events: Causal or Coincidental?*, 351 LANCET 611 (1998).

<sup>45</sup> *Id.* at 611-12.

The authors then proceed to point out potential problems with Wakefield et al.'s research. They state that other researchers, "using more sensitive and specific assays," have not made similar findings of the presence of vaccine viruses in patients with bowel problems.<sup>46</sup> In addition, Chen and DeStefano point out that given the number of children who are vaccinated with the MMR vaccine every year, often during the time when autism first manifests, it is inevitable that some children will be diagnosed with autism after vaccination even if the two events are not causally related. By specifically choosing patients in order to study the connection between the vaccine and bowel disorders, which Wakefield posits as a possible cause of autism, biased case-ascertainment is occurring, which may exaggerate the association.<sup>47</sup> Finally, Chen and DeStefano take issue with the fact that Wakefield and his team did not complete "critical" virological studies in their patients to support their hypothesis linking bowel disorder to the MMR vaccine as a prerequisite for developing autism.<sup>48</sup>

In closing, Chen and DeStefano note that, as a historical matter, concerns about vaccine safety usually increase when the actual disease the vaccine prevents is no longer a threat because of the effectiveness of the vaccine while the number of adverse reactions attributed to the vaccine increases because of widespread use. Some of these attributions may also be false because developmental abnormalities often manifest around the same time that children get vaccinated.<sup>49</sup> Given all this, they argue that it is necessary to use "[e]ffective and credible systems" to evaluate vaccine safety so that causal and coincidental problems can be distinguished from each other. Otherwise, concerns about vaccines that are reported by

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<sup>46</sup> *Id.* at 612.

<sup>47</sup> *Id.*

<sup>48</sup> *Id.*

<sup>49</sup> *Id.*

researches like Wakefield et al. “may snowball into societal tragedies where the media and the public confuse association with causality and shun immunization.”<sup>50</sup> Prophetic words.

### **B. Peltola et al.’s Fourteen Year Study**

A few short months later, *The Lancet* published another article about the MMR vaccine, bowel disease, and autism, based on a fourteen-year study by Heikki Peltola et al.<sup>51</sup> The study is based on data from Finland, which began a vaccination project in 1982 to eradicate MMR diseases in the country. Accordingly, all children in the country were given two doses of the vaccine, once at fourteen to sixteen months of age and again at six years of age. Any adverse reactions to the vaccine were then reported to the National Public Health Institute, which was responsible for overseeing the vaccine program.<sup>52</sup>

In order to determine whether or not there is a connection between the MMR vaccine and bowel disorder or autism, Peltola et al. begin by combing through the adverse reaction reports from 1982 through 1996 to look for any cases where children developed gastrointestinal problems after being vaccinated. Out of the approximately three million doses distributed, thirty-one recipients of the vaccine developed gastrointestinal symptoms after vaccination.<sup>53</sup> The symptoms developed between twenty hours and fifteen days after receiving the vaccine, were relatively mild, and in all but one case, cleared up again within a week.<sup>54</sup> Most importantly, Peltola et al. report that they are unable to find a single case in which a child developed an autistic spectrum disorder after vaccination.<sup>55</sup>

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<sup>50</sup> *Id.*

<sup>51</sup> Heikki Peltola et al., Research Letters, *No Evidence for Measles, Mumps, and Rubella Vaccine-Associated Inflammatory Bowel Disease or Autism in a 14-Year Prospective Study*, 351 LANCET, 1327 (1998).

<sup>52</sup> *Id.* at 1327.

<sup>53</sup> *Id.*

<sup>54</sup> *Id.* at 1327-28.

<sup>55</sup> *Id.* at 1328.

### C. Brent Taylor et al.'s Alternative Approach

While Peltola et al. scrutinize the immunization records of Finland and try to track down cases of autism that developed after receiving the MMR vaccine, Brent Taylor and his team of researchers take a different approach to testing whether the MMR vaccine is causally associated with autism. They start by identifying all children with autism born since 1979 in eight health districts in the United Kingdom and then look to see if there is a change in incidents of autism once the MMR vaccine was introduced in 1988.<sup>56</sup> Although Taylor et al. do find an increase in the incidence of autism in more recent years, they point out that the increase is not causally related to the MMR vaccine because use of the vaccine had plateaued at the time when instances of autism were on the increase.<sup>57</sup> Instead, the researchers postulate that the greater number of autism cases may reflect better training in the medical community to recognize the disorder and/or better recognition of higher functioning children who nonetheless are autistic.<sup>58</sup>

As part of their research efforts, Taylor et al. also investigate whether the time at which children were vaccinated with the MMR vaccine correspond in some way with the age at which autism was diagnosed. Their conclusion: age of diagnosis is not connected to whether or when the vaccine is given.<sup>59</sup> Specifically, regression in behavioral development in autistic children, which Wakefield et al. discussed at length in their paper, is not more common in the months after vaccination.<sup>60</sup> Taylor et al. do find that there is a peak in parents reporting the first signs of behavioral abnormality at eighteen months of age, which results in a clustering effect for reporting problems within six months of obtaining the MMR vaccine. However, the authors

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<sup>56</sup> Brent Taylor et al., *Autism and Measles, Mumps, and Rubella Vaccine: No Epidemiological Evidence for a Causal Association*, 353 LANCET 2026, 2026 (1999).

<sup>57</sup> *Id.* at 2028.

<sup>58</sup> *Id.*

<sup>59</sup> *Id.*

<sup>60</sup> *Id.* at 2029.

attribute this effect to parents estimating the time of onset of behavioral abnormalities to eighteen months of age because they could not recall the actual time of onset.<sup>61</sup> Based on all of the data, Taylor et al. find no support for the hypothesis that the MMR vaccine is causally related to autism.<sup>62</sup>

After Taylor et al. published their paper in *The Lancet*, Wakefield wrote to the journal, criticizing the research on the basis of three perceived weaknesses. First, he takes issue with the case-series method by which Taylor's team carried out the research, stating that it is not an effective way to identify a relationship between exposure and disease where the disease in question manifests gradually such that diagnosis does not occur immediately.<sup>63</sup> Second, Wakefield disapproves of the way Taylor et al. explained away the statistically significant increase in parents' reported concern for their children's behavior that occurred within six months of receiving the MMR vaccine.<sup>64</sup> But the biggest problem, according to Wakefield, is the fact that Taylor et al. failed to mention an MMR catch-up campaign launched in the United Kingdom in 1988 when the vaccine was first introduced. During the catch-up campaign, young children born prior to 1988 who had not received either the mumps or rubella vaccine were given the MMR vaccine instead.<sup>65</sup> Thus, children born in 1986 also received the vaccine and, more significantly, there was a dramatic increase in the development of autism beginning in 1986 as compared to previous years, which still hints at a possible connection between the two. Due to these perceived flaws, Wakefield cautions against accepting Taylor et al.'s research and ultimate conclusions.<sup>66</sup>

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<sup>61</sup> *Id.*

<sup>62</sup> *Id.*

<sup>63</sup> Andrew J. Wakefield, *MMR Vaccination and Autism*, 354 LANCET 949, 949 (1999).

<sup>64</sup> *Id.*

<sup>65</sup> *Id.*

<sup>66</sup> *Id.* at 950.

#### **D. Kaye et al.'s Research Supporting Taylor's Findings and Rejecting the Vaccine-Autism Connection**

Along with Wakefield's criticism of Taylor et al.'s work, *The Lancet* published a reply from Taylor and two other researchers defending their study.<sup>67</sup> They claim that Wakefield misinterpreted their data and results, ending with a statement that they continue to support their conclusion that there is no causal connection between the MMR vaccine and autism.<sup>68</sup> Soon after, James A. Kaye et al. published their own study on the temporal relation between the MMR vaccine and onset of autism, which supported Taylor et al.'s conclusion.<sup>69</sup>

Kaye et al. begin by identifying 305 British children who were diagnosed with autism between the years 1988 and 1999. They obtained information on these children's medical history from the UK general practice research database, which has detailed information on vaccination history.<sup>70</sup> Out of these 305 children, the researchers focus in on 114 boys born between 1988 and 1993 who were diagnosed with autism between the ages of two and five and conduct statistical analysis by annual birth cohort in order to determine the prevalence of autism.<sup>71</sup> Kaye et al. find that the annual incidence of autism in children increased from 0.3 per 10,000 people in 1988 to 2.1 per 10,000 people in 1999.<sup>72</sup> In addition, the risk of autism among boys aged two to five increased nearly fourfold between 1988 and 1993. During this time, however, the rate of MMR vaccination remained constant at ninety-seven percent.<sup>73</sup>

After presenting the results of the statistical analysis, Kaye et al. discuss the implications of the data. Like Taylor et al., they point out that if the MMR vaccine is causally related to

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<sup>67</sup> Brent Taylor et al., *Authors' Reply*, 354 LANCET 950, 950 (1999).

<sup>68</sup> *Id.*

<sup>69</sup> James A. Kaye et al., *Mumps, Measles, and Rubella Vaccine and the Incidence of Autism Recorded by General Practitioners: A Time Trend Analysis*, 322 BRIT. MED. J. 460 (2001).

<sup>70</sup> *Id.* at 461.

<sup>71</sup> *Id.*

<sup>72</sup> *Id.*

<sup>73</sup> *Id.* at 462.



autism, then the prevalence of autism should have plateaued shortly after the vaccine's use became widespread. The fact that this is not the case speaks against a causal connection between the MMR vaccine and autism.<sup>74</sup> Also like Taylor et al., Kaye and his team posit that the increase in rates of autism may be due to increased awareness on the part of the medical community or changing diagnostic criteria.<sup>75</sup>

#### **E. Other Research Rejecting a Connection Between the MMR Vaccine and Autism**

As early as 1999, just a little over a year after Wakefield et al.'s study was published, certain members of the medical community were already calling for an end to research into the connection between autism and vaccination on the grounds that the alleged link had been disproved.<sup>76</sup> And yet, researchers continued to report their findings in subsequent years, perhaps in an attempt to combat the pervasive shadow that the myth cast upon the public's conception of the MMR vaccine.

In 2002, a study based on population data from Denmark was published in *The New England Journal of Medicine*.<sup>77</sup> Madsen et al. look at all children born in Denmark between 1991 and 1998, obtaining information on the children's vaccination status and any diagnosis of autism or autistic spectrum disorders. After analyzing the data, they conclude that there is no increase in the risk of autistic disorder among children who received the MMR vaccine.<sup>78</sup> Additional

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<sup>74</sup> *Id.*

<sup>75</sup> *Id.*

<sup>76</sup> Hilary Bower, *New Research Demolishes Link Between MMR Vaccine and Autism*, 318 BRIT. MED. J. 1643, 1643 (1999) (quoting Norman Begg, head of the Communicable Disease Surveillance Center's immunization division, who argues that research demonstrates that "[the MMR] vaccine causes neither autism nor inflammatory bowel disease" such that the issue should be laid to rest).

<sup>77</sup> Kreesten Meldgaard Madsen et al., *A Population-Based Study of Measles, Mumps, and Rubella Vaccination and Autism*, 347 NEW ENG. J. MED. 1477 (2002).

<sup>78</sup> *Id.* at 1479-80.

evidence for the lack of a causal connection between the vaccine and autism comes from the fact that there is no temporal clustering of autism cases after immunization.<sup>79</sup>

Almost a decade after Wakefield's initial paper, researchers were still publishing papers disproving the link. For example, Tokio Uchiyama et al. conducted a similar population-based study on the use of MMR vaccine in Japan, publishing their results in 2007.<sup>80</sup> The Japanese history with the vaccine provided a unique opportunity to test for a causal connection between it and autism. The vaccine was introduced into Japan in 1989, with the government recommending one dose to be given to children between twelve and thirty-six months of age. Only a few years later, in 1993, the government ceased extensive use of the MMR vaccine because a few cases of aseptic meningitis developed after immunization.<sup>81</sup> Thus, if the MMR vaccine caused autism, incidents of the disorder should have increased shortly after the vaccine was introduced in 1989 and then decreased once the vaccine was no longer in widespread use. To test the link between the MMR vaccine and autism, Uchiyama et al. first compare the presence of regressive symptoms in autistic children who received the MMR vaccine and those who did not. They also look at the proportion of children who had regressive symptoms before, during, and after the MMR vaccine's use in Japan.<sup>82</sup> They find no significant difference in regression between those children who received the MMR vaccine and children who did not. Furthermore, there is no significant increase in the general incidence of regression in the period when the MMR vaccine was used as compared to the years before and after it was administered.<sup>83</sup>

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<sup>79</sup> *Id.* at 1480.

<sup>80</sup> Tokio Uchiyama et al., *MMR-Vaccine and Regression in Autism Spectrum Disorders: Negative Results Presented from Japan*, 37 J. AUTISM DEV. DISORDER 210 (2007).

<sup>81</sup> *Id.* at 211.

<sup>82</sup> *Id.* at 210-11.

<sup>83</sup> *Id.* at 210, 214.

An added bonus of the Uchiyama study is the probable lack of bias in clinicians and parents who participated in the research. Unlike in Europe and the United States, the alleged link between the MMR vaccine and autism was never publicized in Japan. In addition, by the time Wakefield published his first paper and began communicating his concerns to the public, the MMR vaccine had already been taken off the shelf in Japan.<sup>84</sup> Thus, in answering questions about regressive symptoms, parents were not thinking about any possible connection between those symptoms and their children's immunization history, adding credibility to their answers. As the next part of the paper reveals, it was public awareness of the alleged vaccine-autism connection in the Western world that gave life to the myth, ultimately leading to unfortunate consequences.

### **III. The Public's Response**

As many researchers, including several mentioned in Part Two of the paper, have noted, the number of children diagnosed with autism and autistic-spectrum disorders has been increasing in recent times.<sup>85</sup> Autism, depending on severity, can be a devastating disorder for both the children who suffer from it and their parents. Autistic children predominantly suffer deficits in the realm of communication, neither responding to others nor expressing themselves verbally.<sup>86</sup> More severe symptoms of the disorder may include banging one's head against a wall or slapping oneself.<sup>87</sup> Children may also lash out at their surroundings, destroying entire households.<sup>88</sup> In rare instances, parents of autistic children have become so overwhelmed with

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<sup>84</sup> *Id.* at 215.

<sup>85</sup> *Supra* notes 57, 58, and 72 and accompanying text.

<sup>86</sup> MICHAEL G. CHEZ, AUTISM AND ITS MEDICAL MANAGEMENT 27 (2008).

<sup>87</sup> OFFIT, *supra* note 33, at 4 (reporting on parents' experiences with autistic children who destroy entire homes without any malice).

<sup>88</sup> *Id.*

the behavioral difficulties presented by their children, they have killed them in order to escape.<sup>89</sup>

Given the severe toll that the disorder can take on afflicted families, the amount of publicity generated by Wakefield's research becomes more understandable. An identifiable cause may bring researchers one step closer to a cure. At the least, it provides a target for parents' frustrations and supposedly answers the question of "why is my child sick?"

### **A. Popular Media**

The popular press was quick to publicize Wakefield's findings. *The Guardian* and the *Daily Mail* both published articles about the alleged link between the MMR vaccine and autism at the same time that *The Lancet* published Wakefield's article.<sup>90</sup> While neither article definitively linked the vaccine and autism, and both were quick to point out that there was no medical consensus about the finding, both also quoted Wakefield's remarks from his press conference, where he expressed his discomfort with continued use of the MMR vaccine. In the days, months, and years that followed, newspapers kept the story in people's minds, providing periodic updates on the medical debate over the vaccine and playing up the controversy.<sup>91</sup> And sometimes, the popular press published wrenching stories of parents whose children had a negative reaction to the MMR vaccine even though doctors ruled out the vaccine as a cause of the reaction.<sup>92</sup> Such stories served to increase both the fear of the MMR vaccine and the impact of the controversy on the public.

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<sup>89</sup> *Id.* at 5 (reporting on how a twelve-year-old boy with severe autism was killed by his father, who then calmly called the police to report that he had "terminated the life of [his] autistic child.").

<sup>90</sup> Sarah Boseley, *Alert Over Child Jabs*, GUARDIAN (U.K.), Feb. 27, 1998; Jenny Hope, *Ban Three-in-One Jab Urge Doctors After New Fears*, DAILY MAIL (U.K.), Feb. 27, 1998.

<sup>91</sup> *E.g.*, *Fears Over Triple Jab*, DAILY MAIL (U.K.), Mar. 23, 1998; George Gordon & Jenny Hope, *Fear of Link Between Vaccines and Autism*, DAILY MAIL (U.K.), Aug. 17, 1999.

<sup>92</sup> Jenny Hope, *Our Beautiful, Healthy Little Girl Had an MMR Injection. Within Hours, She Was Dying; Parents Call for Triple Vaccine to be Banned*, DAILY MAIL (U.K.), Mar. 15, 1999 (reporting on how parents of baby girl who died shortly after receiving the MMR vaccine blamed said vaccine even though doctors at a hearing on the death ruled out the vaccine as a cause because the fever that resulted came on too quickly).

Later on, when revelations about Wakefield's research and potential conflicts of interest came to light, casting doubt on his findings, the newspapers eagerly reported on these developments as well.<sup>93</sup> Some stories cast Wakefield as a hero fighting against a medical community and government that did not care about children's safety while others reported that Wakefield committed outright fraud.<sup>94</sup> Regardless of the portrayal of Wakefield and the increasing criticisms of his study, the media had done its damage. The public did not necessarily remember or care about Wakefield himself but it did remember the underlying theme of his message: MMR vaccines may cause autism.<sup>95</sup> And this broader theme generated problems that played themselves out in multiple arenas.

## **B. Celebrity Endorsement**

As with many other products and causes, Wakefield's research soon found itself a celebrity endorser who would help spread the message that vaccines pose a danger and may cause autism. Jenny McCarthy, one-time Playboy model turned actress and author, became a spokesperson for the vaccine-autism controversy, giving voice to the concerns of hundreds and thousands of parents, using her fame to help spread a "beware of vaccinations" message. Her passion and zeal in this role came from her own experiences with her son, Evan, who was diagnosed with autism after having multiple seizures at the age of two.<sup>96</sup>

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<sup>93</sup> E.g., Sarah Boseley, *Doctor Behind MMR Scare to Face Four Charges of Misconduct Over Research*, GUARDIAN (U.K.), June 12, 2006; John F. Burns, *British Council Bars Doctor Who Linked Vaccine with Autism*, NEW YORK TIMES, May 25, 2010.

<sup>94</sup> Compare Beezy Marsh, *Doctor Who Warned on MMR Forced Out*, DAILY MAIL (U.K.), Dec. 3, 2001 (reporting that Wakefield, who had become a "pariah" of the Department of Health after he released his findings, had been "forced" out of his job at the Royal Free Hospital), and Editorial, *Autism Fraud*, NEW YORK TIMES, Jan. 13, 2011 (reporting that the *British Medical Journal* considered Wakefield's research for his 1998 paper to be a deliberate fraud).

<sup>95</sup> TAMMY BOYCE, HEALTH, RISK AND NEWS: THE MMR VACCINE AND THE MEDIA 25 (2007).

<sup>96</sup> JENNY MCCARTHY, LOUDER THAN WORDS: A MOTHER'S JOURNEY IN HEALING AUTISM 28, 53 (2007). However, some have raised the possibility that Evan is not actually autistic. Rather, he may have suffered from another childhood neurological disorder, Landau-Kleffner syndrome, which has similar symptoms as autism. Karl Taro Greenfeld, *The Autism Debate: Who's Afraid of Jenny McCarthy?*, TIME, Feb. 25, 2010, available at <http://www.time.com/time/nation/article/0,8599,1967796-1,00.html>.

After Evan was diagnosed, McCarthy began doing research on autism, eventually stumbling onto a website that claimed autism is reversible. In reading the stories from other parents on the site, McCarthy came to believe that the MMR vaccine was the cause of her son's problems.<sup>97</sup> She also became convinced that her ultimate calling was to publicize the information she had learned about autism and share it with other mothers.<sup>98</sup> McCarthy herself has stated, "I will work my ass off, raising awareness for autism and banging down doors to get answers."<sup>99</sup> As part of working to raise awareness, McCarthy has appeared on television shows such as *Oprah*, *20/20*, and *Larry King Live*, where she has repeatedly voiced her concerns about vaccines and autism.<sup>100</sup> For example, in 2008, McCarthy went on *Larry King Live* to speak about autism and said that vaccines play "the largest role" in triggering autism in children.<sup>101</sup> While McCarthy did not go so far as to claim that children should not be vaccinated at all, she expressed concern over the number of vaccines and the schedule for receiving them.<sup>102</sup> When asked if her views on autism were backed by scientific research, McCarthy stated quite frankly that her views were based on anecdotal information from parents of autistic children that she had met over the years, which she equated to science-based information.<sup>103</sup>

And this is the power of McCarthy: while the scientific and medical communities may run experiments and publish findings time and time again, all of which find no causal connection between autism and vaccines, McCarthy gives voice to the parents who struggle daily with raising autistic children, who are trying desperately to understand why their children are sick. Dry science and medical studies are no match for the heart-wrenching stories of children who

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<sup>97</sup> *Id.* at 82-83.

<sup>98</sup> *Id.* at 85.

<sup>99</sup> *Id.* at 189.

<sup>100</sup> Greenfeld, *supra* note 96.

<sup>101</sup> Transcript of *Larry King Live: Jenny McCarthy's Autism Fight*, Apr. 2, 2008, <http://transcripts.cnn.com/TRANSCRIPTS/0804/02/lkl.01.html>.

<sup>102</sup> *Id.*

<sup>103</sup> *Id.*

seem perfectly fine one day only to undergo dramatic developmental and behavioral changes shortly after receiving the MMR vaccine. Until the scientific community can provide a definitive alternative explanation for what causes autism, there will be parents who rely on anecdotes to perpetuate the vaccine-autism myth first publicized by Wakefield. McCarthy, as the most famous of such parents, provides an illustration of how difficult it may be for science to counter the myth: as reports about Wakefield's questionable research methods surfaced and mounting medical evidence rejected a connection between autism and vaccination, McCarthy stood by Wakefield, claiming that the concerns about Wakefield were simply "the allegations of a single British journalist."<sup>104</sup> Instead of seeing the criticism of Wakefield's work as signaling the end of the vaccine-autism debate, McCarthy has become even more determined to look into how vaccines cause autism and "fight for the truth about what's happening to our kids."<sup>105</sup>

### **C. Litigation**

Given the conviction some parents have that vaccines are responsible for their children developing autism and the expenses associated with raising autistic children, it comes as no surprise that angry parents filed lawsuits seeking compensation. In the United States, claims for harm from vaccines are heard in a special Vaccine Court, created through the federal Vaccine Injury Compensation Program ("VICP"). VICP itself was a response to another vaccine scare involving the diphtheria-pertussis-tetanus ("DPT") vaccine in the 1980s.<sup>106</sup> As with the MMR vaccine, the concerns about the DPT vaccine turned out to be unfounded. Despite the scientific evidence, though, sympathetic juries sometimes awarded significant damages to plaintiffs.<sup>107</sup> The

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<sup>104</sup> Jenny McCarthy, *In the Vaccine-Autism Debate, What Can Parents Believe?*, HUFFINGTON POST, Jan. 10, 2011, [http://www.huffingtonpost.com/jenny-mccarthy/vaccine-autism-debate\\_b\\_806857.html](http://www.huffingtonpost.com/jenny-mccarthy/vaccine-autism-debate_b_806857.html).

<sup>105</sup> *Id.*

<sup>106</sup> Stephen D. Sugarman, *Cases in Vaccine Court—Legal Battles over Vaccines and Autism*, 357 NEW ENG. J. MED. 1275, 1276 (2007).

<sup>107</sup> *Id.*

combination of increased litigation and difficulty in obtaining liability insurance threatened to drive vaccine manufacturers out of the business of making vaccines.<sup>108</sup> In an effort to continue protecting the population through vaccination, Congress created VICP with the goal of streamlining vaccine claims while protecting manufacturers from massive payouts for those rare instances where a patient suffers a severe adverse reaction to a vaccine.

Under the VICP, a plaintiff alleging harm from a vaccine needs to show some causal connection between the administered vaccine and the harm suffered. An advisory committee keeps an up-to-date list of known side effects of each vaccine and if a child suffers from one of these recognized side effects shortly after receiving the vaccine, causation is presumed.<sup>109</sup> If a child suffers from an adverse effect that is not on the list, however, it is up to the child's family to show that the vaccine was the cause of the adverse reaction.<sup>110</sup> Assuming that causation is proven, a plaintiff can receive compensation for medical expenses, lost future income, and up to \$250,000 for pain and suffering.<sup>111</sup> To free vaccine manufacturers from having to pay the awards, the VICP created a trust, funded by a fee on each vaccine administered.<sup>112</sup>

Autism has not been listed as a recognized adverse effect for any vaccines. Thus, parents seeking compensation through the VICP have the burden of showing the connection between the vaccines their children received and autism. To win, parents have to show that the vaccine was a substantial factor in causing the harm and the link must be supported by "reputable medical or scientific explanation."<sup>113</sup> The potential difficulty of this burden, especially given the lack of

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<sup>108</sup> Michael Greenberger, *The 800 Pound Gorilla Sleeps: The Federal Government's Lackadaisical Liability and Compensation Policies in the Context of Pre-Event Vaccine Immunization Programs*, 8 J. HEALTH CARE L. & POL'Y 7, 13 (2005).

<sup>109</sup> Sugarman, *supra* note 106, at 1276.

<sup>110</sup> *Id.*

<sup>111</sup> *Id.*

<sup>112</sup> *Id.*

<sup>113</sup> *Cedillo v. Sec'y of Health and Human Services*, No. 98-916V, 2009 WL 331968, at \*2, (Fed. Cl. Feb. 12, 2009) (quoting *Althen v. Sec'y of Health and Human Services*, 418 F.3d, 1274, 1278 (1991)).



consensus about the medical evidence, did not deter parents from filing claims. Between 2001 and 2007, over five thousand autism claims were filed with the Vaccine Court.<sup>114</sup> Indeed, in the first decade of the 21st century, approximately seventy-five percent of the cases filed under the VICP have been autism-related.<sup>115</sup>

Given the staggering number of autism claims, an “Omnibus Autism Proceeding” (“OAP”) was developed whereby the Vaccine Court would first look to the evidence and decide whether vaccines can cause autism in general. If the answer to this first inquiry was in the affirmative, then the Vaccine Court would proceed on to adjudicating individual cases.<sup>116</sup> The OAP began collecting general information in 2002, eventually amassing thousands of pages of medical evidence and expert testimony. Finally, in 2007, several test cases involving the issue of general causation were presented to the three special masters who were in charge of the OAP.<sup>117</sup> The first three test cases all involved claims that the MMR vaccine, either on its own, or in combination with thimerosal, a mercury-based preservative sometimes put into vaccines, caused autism in the plaintiff children.<sup>118</sup> In all three cases, the special masters held that the plaintiff

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<sup>114</sup> Sugarman, *supra* note 106, at 1275-76.

<sup>115</sup> Barry Meier, *Vaccine Cases to be Heard by Justices*, NEW YORK TIMES, Oct. 12, 2010.

<sup>116</sup> *Cedillo*, 2009 WL 331968 at \*8.

<sup>117</sup> *Id.* at \*9-\*10.

<sup>118</sup> *Id.* at \*15; *Hazlehurst v. Sec’y of Health and Human Services*, No. 03-654V, 2009 WL 332306, at \*1, (Fed.Cl. Feb. 12, 2009); *Snyder v. Sec’y of Health and Human Services*, No. 01-162V, 2009 WL 332044, at \*1, (Fed.Cl. Feb. 12, 2009).

parents failed to demonstrate that the MMR vaccine was the cause of their children's autism.<sup>119</sup>

These decisions were upheld on appeal.<sup>120</sup>

In non-autism related claims under the VICP, parents who failed to demonstrate a causal connection generally did not attempt to obtain compensation in some other manner.<sup>121</sup> However, in the autism context, there is reason to believe that parents will not give up so easily, despite the medical evidence and court decisions to the contrary. First, these parents are well-organized and have the support of lawyers as well as several prominent congressmen.<sup>122</sup> Second, and more importantly, they absolutely believe in their claims, regardless of what the medical data shows. Those who believe in the vaccine-autism connection have dismissed the adverse findings of the special masters, claiming that the OAP arrangement will never result in a fair ruling for plaintiffs.<sup>123</sup> That this criticism is used to reject the Vaccine Court's proceedings, despite the fact that it was the plaintiffs' attorneys who initially proposed the omnibus proceeding,<sup>124</sup> demonstrates how strongly some parents feel about the vaccine-autism connection and how difficult it may ultimately be to put an end to the controversy.

#### **D. Congressional Action**

Courts were not the only governmental body that became involved in the vaccine-autism debate. Beginning in 2000, Congress conducted several hearings on possible links between

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<sup>119</sup> *Cedillo*, 2009 WL 331968 at \*67 (“Petitioners have failed to demonstrate that it is ‘more probable than not’ either that the MMR vaccine can cause or contribute to autism in general, or that a MMR vaccination did cause or contribute to Michelle's autism”); *Hazlehurst*, 2009 WL 332306 at \*172 (concluding that “the combination of the thimerosal-containing vaccines and the MMR vaccine are not causal factors in the development of autism”); *Snyder*, 2009 WL 332044 at \*137 (“[P]etitioners have failed to demonstrate that the MMR vaccine can cause autism, even in the highly circumscribed subset of children with regressive [autism spectrum disorder] and gastrointestinal symptoms”).

<sup>120</sup> *Cedillo v. Sec’y of Health and Human Services*, 617 F.3d 1328 (Fed. Cir. 2010); *Hazlehurst v. Sec’y of Health and Human Services*, 604 F.3d 1343 (Fed. Cir. 2010); *Snyder v. Sec’y of Health and Human Services*, 88 Fed.Cl. 706 (Fed. Cl. 2009).

<sup>121</sup> *See Sugarman*, *supra* note 106, at 1277.

<sup>122</sup> *Id.*

<sup>123</sup> Donald G. McNeil, Jr., *3 Rulings Find No Link to Autism in a Mercury Preservative in Vaccines*, NEW YORK TIMES, Mar. 13, 2010.

<sup>124</sup> *Cedillo v. Sec’y of Health and Human Services*, No. 98-916V, 2009 WL 331968, at \*8, (Fed. Cl. Feb. 12, 2009).

vaccines and autism. These hearings before the Committee on Government Reform were chaired by Congressman Dan Burton of Indiana. At the first hearing, Congressman Burton opens the meeting with stories about his own grandchildren's negative experiences with vaccines. According to Burton, his granddaughter stopped breathing and had to be rushed to the hospital after receiving the Hepatitis B vaccine while his grandson became autistic after receiving a series of vaccines.<sup>125</sup> Burton then launches into a discussion on the possible link between autism and vaccination, stating that forty-seven percent of parents who provided pictures of their children for an autism rally felt that autism was linked to vaccines.<sup>126</sup> Although Burton makes clear that he is not anti-vaccinations and that he knows not all cases of autism are caused by vaccines,<sup>127</sup> the record of the hearing suggests that he was far from impartial on the issue.

It must be noted as an initial matter that many of those invited to testify in person, including parents of autistic children and Wakefield himself, were more accepting of the vaccine-autism connection while many of the individuals and groups who were not invited to testify were those who submitted letters and statements expressing concern that the hearing would perpetuate the false perception that vaccines cause autism.<sup>128</sup> Brent Taylor, whose research contradicting Wakefield was discussed earlier, also testified at the hearing, presenting his evidence to the Committee. After Taylor concludes his statement, Burton calls a witness from the audience to cast doubt on the credibility of Taylor's research method, a move that goes against the rules of the Committee. This unusual procedure prompts Congressman Waxman of California to comment that Burton's act of calling an unexpected witness just because Taylor did

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<sup>125</sup> *Autism: Present Challenges, Future Needs—Why the Increased Rates?: Hearing Before the H. Comm. on Gov. Reform*, 106th Cong. 2 (2000) [hereinafter *Autism: Present Challenges Hearing*].

<sup>126</sup> *Id.*

<sup>127</sup> *Id.* at 3.

<sup>128</sup> *See id.* at 11-25.

not present testimony that fit with Burton's preconceived notions turned the hearing "more into a circus than a genuine fact-finding opportunity."<sup>129</sup>

After justifying the calling of the unexpected witness on unexplained "extenuating circumstances,"<sup>130</sup> Burton goes on to express concern with the fact that another expert witness who denied the vaccine-autism connection was funded by Merck, which Burton thinks hints at a conflict of interest or bias towards vaccines.<sup>131</sup> Based on the way the hearing is handled, (i.e., inviting parents who link vaccines to the development of autism to speak, calling unanticipated witnesses to question the methodology of researchers who disagree with Wakefield's conclusions, and not inviting experts from various medical and immunological associations who may deny a causal connection between autism and vaccination) Waxman expresses concern that the entire hearing is meant to establish a particular point of view, namely Burton's view that vaccines are linked to autism.<sup>132</sup>

One year later, Burton chaired another hearing on the increased rates of autism.<sup>133</sup> After retelling the story of his grandson's descent into autism shortly after being vaccinated,<sup>134</sup> Burton discusses the recent report released by the Institute of Medicine's ("IOM") Committee on Immunization Safety Review on the MMR vaccine. According to Burton, while the report itself does not conclusively prove or disprove a link between the vaccine and autism, various media outlets had all begun to report that there was no connection, which Burton views as a

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<sup>129</sup> *Id.* at 187.

<sup>130</sup> *Id.* at 188.

<sup>131</sup> *Id.* at 322-23.

<sup>132</sup> *Id.* at 190-91.

<sup>133</sup> *Autism—Why the Increased Rates? A One-Year Update: Hearing Before the H. Comm. on Gov. Reform*, 107th Cong. (2001) [hereinafter *One-Year Update Hearing*].

<sup>134</sup> *Id.* at 2.

“disservice . . . to the American people.”<sup>135</sup> Throughout the rest of the hearing, Burton time and time again questions various aspects of both the IOM Committee and its report findings.

First, when the chairwoman of the IOM Committee, Dr. Marie McCormick, testifies before the congressional Committee and states that the MMR vaccine has not been shown to be a contributing factor in autism, Burton pushes back again and again, asking if McCormick knows in absolute terms that this is the case,<sup>136</sup> getting himself quite worked up in the process.<sup>137</sup> The problem with Burton’s reasoning is that autism is a disorder whose origins are currently shrouded in mystery. That the Review Committee is unwilling to say definitively that vaccines do not ever play any part in the development of autism is a far cry from saying that vaccines cause autism. Unfortunately, it is this latter message that Burton seems most enthusiastic about spreading, regardless of its veracity.

After the heated exchange with McCormick, Burton goes on to question whether or not the members of the IOM Committee had conflicts of interest in terms of funding from pharmaceutical companies. When the representative from the IOM, Ms. Stoiber, testifies that all Committee members were carefully scrutinized to make sure that none of them were being funded in any way by the pharmaceutical companies, Burton shifts the attack. He first tries to raise doubts about IOM’s methods for choosing reviewers for its report, suggesting that only reviewers who were skeptical of the vaccine-autism link were chosen.<sup>138</sup> After Stoiber repeatedly assures Burton that reviewers are chosen from all sides of the issue,<sup>139</sup> Burton again raises the

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<sup>135</sup> *Id.*

<sup>136</sup> *Id.* at 215.

<sup>137</sup> Brian Vastag, *Congressional Autism Hearings Continue: No Evidence MMR Vaccine Causes Disorder*, 285 J. AM. MED. ASS’N 2567, 2567 (2001) (“At his latest congressional hearing looking into possible links between autism and childhood vaccines, Burton . . . slammed down a recent Institute of Medicine (IOM) report—which concluded there was no evidence that the . . . [MMR vaccine] leads to autism—and shouted, red-faced, ‘You don’t know there’s no link, do you? Do you?’”).

<sup>138</sup> *One-Year Update Hearing*, *supra* note 133, at 216.

<sup>139</sup> *Id.* at 216-17.

issue of funding, asking if any of the reviewers were being funded by pharmaceutical companies.<sup>140</sup> He raises this point even though Stoiber informs him that reviewers' comments are given anonymously, that several reviewers were sympathetic to the vaccine-autism link, and that reviewers have no ability to change the IOM report in any way.<sup>141</sup> Having been rebuffed again, Burton raises a third alleged problem: that some of the IOM Committee members worked at universities that, in some way, received funding from the pharmaceutical companies.<sup>142</sup> When Stoiber responds that the IOM scrutinizes only the individual Committee members and the funding their labs receive,<sup>143</sup> Burton finally seems satisfied that he has discovered a problem with the IOM report. Interestingly, Burton never demonstrates much concern with either the direct or indirect funding of those who testified in favor of the vaccine-autism connection. As discussed in the next section of the paper, he should have been far more concerned about Wakefield's financial motivations than the attenuated chain of financial bias he tries to create between some IOM Committee members, the universities where they are employed, and the pharmaceutical companies.

As chairman of the House Committee on Government Reform, Burton convened multiple hearings on autism and vaccines. As Waxman notes in his opening remarks at yet another such hearing in 2002, Burton's hearings had the positive effect of drawing more attention to vaccine safety, prompting researchers to devote attention to the issue.<sup>144</sup> And time after time, scientists conducting research and expert panels reviewing that research concluded that vaccines are safe.<sup>145</sup> Unfortunately, though, Burton has not accepted that research; instead, he has convened

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<sup>140</sup> *Id.* at 217.

<sup>141</sup> *Id.* at 216.

<sup>142</sup> *Id.* at 220.

<sup>143</sup> *Id.*

<sup>144</sup> *The Status of Research into Vaccine Safety and Autism: Hearing Before the H. Comm. on Gov. Reform*, 107th Cong. 24 (2002).

<sup>145</sup> *Id.*

additional hearings, “repeatedly provid[ing] a forum for unsubstantiated allegations about vaccine safety that have alarmed and confused parents.”<sup>146</sup> At the same time that evidence of vaccine safety has grown, concerns about their safety have also grown, possibly having detrimental effects on immunization rates.<sup>147</sup> Until researchers discover what exactly causes autism, it may be impossible for scientists to say conclusively that vaccines play no role whatsoever in the disorder. However, the fact that researchers cannot prove a negative fact with one hundred percent certainty should not be used to justify continued congressional hearings into the alleged vaccine-autism link. Continued congressional attention to this largely disproved link may play up the controversy in the minds of the public, perpetuating unfounded fears about vaccines.

#### **IV. Problems with Wakefield and his Research**

As alluded to in the discussion of Burton’s congressional hearings, his fear that opponents of the vaccine-autism connection may have been biased for financial reasons was more properly directed at Wakefield. After his 1998 paper was published, it came to light that Wakefield had conflicts of interest that cast doubt on his findings. In the end, *The Lancet* would retract Wakefield et al.’s 1998 paper and Wakefield himself would be stricken from the United Kingdom medical register.

In 2007, the General Medical Council (“GMC”) of the United Kingdom launched an investigation into Wakefield’s conduct that lasted until 2010. Ultimately, the GMC panel found that from the very beginning, Wakefield had a financial conflict of interest. As the panel explained, two years before he published his 1998 paper, Wakefield was contacted by Richard Barr, a solicitor who was interested in bringing a lawsuit against the manufacturers of the MMR

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<sup>146</sup> *Id.*

<sup>147</sup> *Id.*

vaccine. In order to have a legitimate claim, Barr needed Wakefield to provide evidence that the vaccine had harmed recipients.<sup>148</sup> In exchange for his assistance, Wakefield received two payments of £25,000 (approx. \$40,000) from the Legal Aid Board, which was helping to fund Barr's lawsuit.<sup>149</sup> Later that same year, Wakefield submitted an application to the ethics committee of the Royal Free Hampstead National Health Service ("NHS") Trust seeking approval to conduct research into a connection between the MMR vaccine and digestive disorders, the possible harm Wakefield was documenting for Barr's lawsuit and the topic of his 1998 paper.<sup>150</sup> In his application, Wakefield did not disclose either his connection with Barr's lawsuit or the funding he was receiving from Barr. The GMC concluded that this nondisclosure was contrary to Wakefield's responsibilities and deprived the Royal Free ethics committee of material information that would have aided it in determining the ethical implications of his proposed research.<sup>151</sup>

A similar nondisclosure occurred in the published version of the 1998 paper. There, when discussing how the study was funded, Wakefield et al. only credit the Special Trustees of Royal Free Hampstead NHS Trust and the Children's Medical Charity, saying nothing about Barr's potential lawsuit and the £50,000 Wakefield had received from the Legal Aid Board to help Barr find a connection between the MMR vaccine and injury to children.<sup>152</sup> This omission was actually noted by Barr, who admitted to funding *The Lancet* research, when he first saw the article.<sup>153</sup> In the years that followed, Wakefield would be paid a total of over £400,000 (over

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<sup>148</sup> *Fitness to Practice Panel Hearing: Hearing Before the General Medical Council*, 4 (2010), available at <http://briandeer.com/solved/gmc-charge-sheet.pdf> [hereinafter *GMC Hearing*].

<sup>149</sup> *Id.* at 4-6.

<sup>150</sup> *Id.* at 7.

<sup>151</sup> *Id.* at 11.

<sup>152</sup> See Wakefield et al., *supra* note 30, at 641.

<sup>153</sup> Brian Deer, *How the Vaccine Crisis was Meant to Make Money*, 342 BRIT. MED. J. 136, 139 (2011) ("[Barr] said he paid for the *Lancet* research [and] . . . ['remember[s] noting at the time that the funding acknowledgment wasn't [in the 1998 paper']").



\$600,000) in fees by the Legal Aid Board and Barr for his work.<sup>154</sup> If Burton believes that a researcher may be tainted because the university he works for receives funding in some capacity from pharmaceutical companies, then the fact that Wakefield was directly being paid to find a problem with the MMR vaccine should raise serious concerns about his objectivity and trustworthiness.

Such concerns about objectivity would not be unfounded. Aside from the funding issue, the 1998 paper also had problems relating to its research. First, Barr sent out a newsletter to his clients, telling them to contact Wakefield if their children had certain symptoms possibly related to Crohn's disease. In the same newsletter, Barr wrote that Wakefield had "depressing views about the effect of vaccines on the nation's children."<sup>155</sup> Thus, Wakefield was able to choose test subjects from a very specific pool of potential applicants already predisposed to demonstrating a connection between vaccines and adverse health problems. In contrast, his 1998 paper describes the patients in his study as having been "consecutively" and "self-referred" to the gastroenterology department of the Royal Free hospital,<sup>156</sup> The GMC concluded that this language was irresponsible, misleading, and contrary to Wakefield's duty to provide accurate information in his publication because it implied routine referrals to the Royal Free Hospital when, in reality, Wakefield was actively involved in seeking out the children for his study.<sup>157</sup> The GMC also criticized Wakefield's response to a letter to *The Lancet* that raised a possible selection bias in his study. By replying that all the children had been referred through normal channels on the merits of their symptoms, Wakefield further acted in a dishonest and

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<sup>154</sup> Brian Deer, *MMR Scare Doctor Got Legal Aid Fortune*, SUNDAY TIMES (U.K.), Dec. 31, 2006.

<sup>155</sup> Brian Deer, *How the Case Against the MMR Vaccine was Fixed*, 342 BRIT. MED. J. 77, 81 (2011) [hereinafter Deer, *Case Against MMR Fixed*].

<sup>156</sup> Wakefield et al., *supra* note 30, at 637, 639.

<sup>157</sup> GMC Hearing, *supra* note 148, at 45-46.

irresponsible manner.<sup>158</sup> These findings by the GMC were cited by *The Lancet* when it issued a formal retraction of Wakefield et al.'s 1998 paper.<sup>159</sup>

In addition to the financial conflict of interest and dishonesty regarding the subject selection process, Wakefield was also guilty of falsifying data for his study. Of the twelve children that Wakefield studied for his 1998 paper, he reported that six of them had three key features supporting a connection between the MMR vaccine, gastrointestinal problems, and regressive autism. A comparison with the actual NHS medical records of the children, however, shows that none of the children in the study had all three features.<sup>160</sup> For example, a crucial link in Wakefield's theory is that the onset of symptoms and behavioral changes in children occurred very shortly after receiving the MMR vaccine. Indeed, in his study, he reports that the average length of time between vaccination and behavioral abnormalities for eight of the children was 6.3 days.<sup>161</sup> But actual NHS records indicate that, at most, only two of the children experienced onset of symptoms shortly after receiving the MMR vaccine.<sup>162</sup> For the rest of the children, many had been documented as having developmental problems before receiving the MMR vaccine.<sup>163</sup> Based on this evidence, it seems clear that Wakefield had an agenda when he began his research in 1996—to link the MMR vaccine to some kind of injury in its recipients. The agenda was based on Wakefield's financial interest in a lawsuit against MMR manufacturers. In pursuit of the agenda, Wakefield was willing to falsify research data. The problem with Wakefield's

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<sup>158</sup> *Id.* at 47.

<sup>159</sup> Editors of *The Lancet*, *Retraction—Ileal-Lymphoid-Nodular Hyperplasia, Non-Specific Colitis, and Pervasive Developmental Disorder*, 375 LANCET 445, 445 (2010) ("In particular, the claim[] in the original paper that children were 'consecutively referred' . . . ha[s] been proven to be false. Therefore we fully retract this paper from the published record").

<sup>160</sup> Deer, *Case Against MMR Fixed*, *supra* note 155, at 80.

<sup>161</sup> Wakefield et al., *supra* note 30, at 638.

<sup>162</sup> Deer, *Case Against MMR Fixed*, *supra* note 155, at 80.

<sup>163</sup> *Id.* at 79-80 (For example, child 4 and child 8 from Wakefield et al.'s study had "developmental delays . . . noted before MMR vaccination." Also, child 1's mother expressed concern that he could not hear properly at nine months, a possible symptom of autism, while a neurologist noted normal development of child 1 until eighteen months of age, even though he had received the MMR vaccine at twelve months of age).

actions, as the GMC investigative panel found, was that Wakefield should have known his paper would have major public health implications such that he was under a duty to make sure that the factual information in the publication was true and accurate.<sup>164</sup>

The GMC investigation also concluded that Wakefield acted unethically with regard to the children in the original study. In the process of conducting his research, Wakefield subjected children in the study to various tests, including colonoscopies, lumbar punctures, and various blood and urine tests, just to name a few procedures. According to the GMC, Wakefield caused the children to undergo investigative procedures for research that did not have the approval of the Royal Free ethics committee.<sup>165</sup> Furthermore, and perhaps even worse, he acted in a manner that was contrary to the clinical interests of the children.<sup>166</sup> Wakefield tried to defend himself on the ground that he was only acting as an administrator, but the GMC determined that he was the one who actually ordered the investigations.<sup>167</sup>

Based on the breadth of Wakefield's misconduct as documented by the GMC investigative committee, a Fitness to Practice Panel found Wakefield guilty of serious professional misconduct.<sup>168</sup> When it came time to decide on an appropriate sanction for Wakefield's conduct, the Fitness to Practice Panel concluded that the totality of Wakefield's transgressions merited the severest punishment possible: being erased from the medical register. The severe response was also seen as necessary to protect patients, given Wakefield's "continued lack of insight as to his misconduct."<sup>169</sup> And indeed, in an interview he gave after being struck

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<sup>164</sup> *GMC Hearing, supra* note 148, at 43.

<sup>165</sup> *Id.* at 13 (child 2), 16 (child 1), 18 (child 3), 22 (child 4), 25 (child 6), 27 (child 9), 31 (child 5), 34 (child 12), 37 (child 8).

<sup>166</sup> *Id.* at 15 (child 2), 18 (child 1), 21 (child 3), 24 (child 4), 29 (child 9), 32 (child 5), 36 (child 12), 38 (child 8), 40 (child 7).

<sup>167</sup> *Id.* at 14-15 (child 2), 23 (child 4), 32 (child 5), 36 (child 12), 40 (child 7).

<sup>168</sup> GMC, *Determination on Serious Professional Misconduct (SPM) and Sanction*, 7 (May 24, 2010), [http://www.gmc-uk.org/Wakefield\\_SPM\\_and\\_SANCTION.pdf\\_32595267.pdf](http://www.gmc-uk.org/Wakefield_SPM_and_SANCTION.pdf_32595267.pdf).

<sup>169</sup> *Id.* at 9.

off the register, Wakefield stated that the outcome of the hearing was a foregone conclusion due to government pressure and that he would continue his research.<sup>170</sup> One can only hope that any future research he conducts will not be found to suffer from serious ethical violations.

## **V. Aftermath of the Myth**

After Wakefield published his paper, the public began losing faith in the MMR vaccine, despite multiple studies refuting Wakefield's hypothesis and efforts by various health agencies to publicize the evidence contradicting Wakefield. Lost confidence translated into decreased vaccination rates, which allowed measles to make a comeback. In 2006, Britain suffered from "its worst measles outbreak since the MMR jab was introduced."<sup>171</sup> A teenage boy actually died after contracting the disease; the first death from measles in Britain in fourteen years.<sup>172</sup> The upward trend continued in 2007, with 990 reported cases of measles, and in 2008, with 1348 cases.<sup>173</sup> Back in 1998, the year when Wakefield's paper was published, there were only 56 cases in England and Wales.<sup>174</sup> The United States also experienced increased measles cases, although the vaccination rate remained relatively high.<sup>175</sup> Despite the fact that medicine has come a long way since the pre-vaccine days, measles can still be quite serious, especially because doctors are now unfamiliar with the disease, thanks to the MMR vaccine's effectiveness.<sup>176</sup> Potentially fatal complications that can develop from the measles include pneumonia, hepatitis, and swelling of

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<sup>170</sup> Sophie Borland, *MMR Doctor Struck Off*, DAILY MAIL (U.K.), May 25, 2010.

<sup>171</sup> Fiona Macrae, *Britain Hit by Massive Outbreak of Measles*, DAILY MAIL (U.K.), June 15, 2006.

<sup>172</sup> Nicola Woolcock & Nigel Hawkes, *Decline in MMR Uptake Blamed for Measles Death*, TIMES (U.K.), Apr. 3, 2006.

<sup>173</sup> Sarah Boseley, *National Watchdog Reports Sharp Increase in Childhood Measles*, GUARDIAN (U.K.), Feb. 6, 2009.

<sup>174</sup> Sarah Boseley, *How a Crisis in Confidence in MMR Led to the Return of a Disease Doctors Hoped Was a Thing of the Past: Claimed Link to Autism Led to Slump in Vaccinations: Britain Rejoins Countries with Indigenous Measles*, GUARDIAN (U.K.), Feb. 5, 2008.

<sup>175</sup> Gardiner Harris, *Measles Cases Grow in Number, and Officials Blame Parents' Fear of Autism*, NEW YORK TIMES, Aug. 22, 2008.

<sup>176</sup> Macrae, *supra* note 171.

the brain.<sup>177</sup> Short of death, measles may also cause severe chronic dementia<sup>178</sup> or blindness in rare cases.<sup>179</sup> It is unfortunate that some children now risk developing these serious complications because of Wakefield's actions.

Besides the increase in measles cases, there have also been other long-term negative consequences from Wakefield's theory. First, his research has contributed to growing fears of vaccines in general, serving as a springboard for new theories about vaccines and autism. As the MMR-autism link began to crumble, those who were skeptical of vaccines introduced a new idea for how vaccines caused autism: thimerosal. Thimerosal is a preservative derived from mercury that is added to vaccines to prevent multi-dose vaccine vials from being contaminated by bacteria. Multi-dose vials help keep down the cost of vaccines by reducing expenditures on packaging.<sup>180</sup> Mercury itself may do severe damage to the nervous system and, as the hypothesis went, the mercury derivative in vaccines could be linked to autism, which manifested the same symptoms as mercury poisoning.<sup>181</sup> Eventually, just like the MMR vaccine-autism hypothesis, the thimerosal-autism hypothesis fell apart. The IOM reviewed all available data and concluded that "the evidence favors rejection of a causal relationship between thimerosal-containing vaccines and autism."<sup>182</sup> More recently, the claim has become that the sheer number of vaccines and the multitude of ingredients in vaccines together, somehow, are causally connected to autism.<sup>183</sup>

These varying theories about how vaccines cause autism have had the unfortunate effect of creating long-lasting distrust of vaccines. For example, one recent study found that one in four

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<sup>177</sup> *Id.*

<sup>178</sup> *One-Year Update Hearing*, *supra* note 133, at 222.

<sup>179</sup> Boseley, *supra* note 174.

<sup>180</sup> OFFIT, *supra* note 33, at 62-63.

<sup>181</sup> S. Bernard et al., *Autism: A Novel Form of Mercury Poisoning*, 56 MED. HYPOTHESES 462 (2001).

<sup>182</sup> INSTITUTE OF MEDICINE, IMMUNIZATION SAFETY REVIEW: VACCINES AND AUTISM 152 (2004), available at [http://books.nap.edu/catalog.php?record\\_id=10997](http://books.nap.edu/catalog.php?record_id=10997).

<sup>183</sup> For example, Jenny McCarthy stated on *Larry King Live* that children are given too many vaccines too soon and that toxins such as mercury, ether, and aluminum need to be removed from vaccines. Transcript of *Larry King Live*, *supra* note 101.

parents in the United States believes that some vaccines cause autism in children.<sup>184</sup> Such fears have contributed to parents' decisions not to vaccinate their children against certain diseases.<sup>185</sup> The obvious problem with this is that children then become unprotected from diseases that can also cause serious problems. It is true that the IOM Committee charged with reviewing vaccine safety has been unable to definitively rule out a causal connection between autism and vaccines, as Congressman Burton was eager to point out, but the great weight of the evidence disfavors the connection. That there may be some interplay between vaccines and autism in very rare instances, however, does not warrant widespread changes in vaccination policy. After all, vaccines are known to cause serious adverse reactions in very rare instances, but on the whole, government health agencies, in creating recommended vaccine schedules for their citizens, have determined that the overall benefits from large-scale vaccination outweigh the risk posed by those rare cases where serious problems develop.

In addition to decreased vaccination, the vaccine-autism controversy has had the negative consequence of diverting precious resources away from autism research. There has been an increase in autism rates in recent years, with conservative estimates indicating that one in five hundred children has the disorder.<sup>186</sup> For parents who have autistic children, living with them can be "hell," as the children lash out at their surroundings during outbursts.<sup>187</sup> Moreover, the costs of raising autistic children can be astounding. One study from the Massachusetts Institute of Technology found that the cost for raising an autistic child from birth to seventy years is between \$3.5 to \$4 million, ninety percent of which is for medical care and assistance.<sup>188</sup> Clearly, autism

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<sup>184</sup> Roni Caryn Rabin, *1 in 4 Parents Link Autism to Vaccines*, NEW YORK TIMES, Mar. 9, 2010.

<sup>185</sup> *See id.* (noting that one in eight parents have rejected at least one recommended vaccine, including the chickenpox vaccine and the bacterial meningitis vaccine).

<sup>186</sup> *One-Year Update Hearing*, *supra* note 133, at 1.

<sup>187</sup> *Autism: Present Challenges Hearing*, *supra* note 125, at 56.

<sup>188</sup> CHEZ, *supra* note 86, at 115.

is a serious and growing problem that requires the attention of the medical community. However, resources are not unlimited; whatever resources are spent on disproving the vaccine-autism myth then become unavailable for more promising studies into the actual causes of the disorder. As Congressman Waxman, whose own district has a new diagnosis of autism every three hours, has noted, given the finite resources available as well as the medical consensus, it no longer makes sense to continue to disprove the vaccine-autism myth.<sup>189</sup> But as long as vaccine myths persist, scientists will have to act defensively, dedicating their efforts to disproving those myths, rather than proactively studying autism itself.

## **VI. Lessons for the Future**

If public confidence in vaccines is to be restored and the myth laid to rest, it is necessary both to understand how the myth has persisted despite copious evidence refuting it and to address difficult questions about individual versus public health. First, as to the myth's persistence, the importance of both the media and the Internet cannot be discounted. As detailed in Part Three of the paper, the media was a key player in spreading the myth to the public and in keeping the myth alive by publishing further articles with research updates,<sup>190</sup> by producing television shows about the controversy,<sup>191</sup> and, in later years, even after the myth had largely been rejected, by continuing to give voice to the myth's supporters in the name of balanced journalism.<sup>192</sup>

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<sup>189</sup> See *One-Year Update Hearing*, *supra* note 133, at 224.

<sup>190</sup> E.g., Beezy Marsh, *New Evidence 'Shows MMR Link to Autism'*, DAILY MAIL (U.K.), Aug. 9, 2002; Sarah Boseley, *MMR Links to Autism Dismissed by Huge Study*, GUARDIAN (U.K.), Feb. 5, 2008.

<sup>191</sup> OFFIT, *supra* note 33, at 22-23 (discussing a docudrama that aired in Britain in 2003, *Hear the Silence*, about Wakefield's struggle to bring his research to the attention of the public, including a supposed plot by public health officials to discredit his work as well as intimidation from the drug companies).

<sup>192</sup> E.g., Jenny McCarthy's appearance on *Larry King Live* in 2008, years after researchers and the IOM published studies and reports rejecting a vaccine-autism connection, as the "co-host" of a show entitled *Autism: Solving the Puzzle*. Transcript of *Larry King Live*, *supra* note 101.

In addition to the media coverage, the Internet has also been critical to the myth's perseverance. While the media may pique parents' interest, it is the Internet that can serve as the provider of vast amounts of (mis)information. For example, Jenny McCarthy, in trying to treat her son's disorder, frequently went onto Google to find information. She goes so far as to state at the beginning of her book that she "should have a doctorate in Google research, what with the time [she] spent online trying desperately to understand what was happening to [her] baby."<sup>193</sup> Researching possible causes and treatments for a child's health problems is not problematic in and of itself. The problem with conducting that research on the Internet, however, is that incorrect information may be presented to the researcher. The Internet is a great equalizer: anyone can put their theories out there for the public to review. Unfortunately, with so many different speakers on the Internet, those with actual expertise become just another voice, another opinion, and not necessarily the one given the greatest weight. And once a theory, or in this case a myth, is introduced to the world through the Internet, it becomes impossible to take it back, even if the theory itself turns out to be incorrect.

All this is not to say that the media and the Internet are the enemies of those who are fighting to put the vaccine-autism myth to rest. Both are tools that can be used to aid the cause, but they must be used effectively. Parents of autistic children have been very successful at using the Internet to create networks and to share their stories. And those stories can be very compelling. When thousands of parents each tell a similar story of their children getting vaccinated and suddenly regressing behaviorally, no matter what the science demonstrates, it is difficult to disregard those stories. In a 2010 interview for a *Frontline* documentary about the vaccine-autism controversy, J.B. Handley, co-founder of Generation Rescue, Jenny McCarthy's autism organization, and father to an autistic child, stated quite frankly:

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<sup>193</sup> MCCARTHY, *supra* note 96, at 11.



I don't give a [expletive] about what the MMR said. My kid got six vaccines in one day, and he regressed. You don't have any science that can show me that the regression wasn't triggered by the six vaccines. What the parents are saying is, "I went in for a vaccine appointment. My kid got six vaccines, and they regressed."<sup>194</sup>

Given this kind of strong response, it becomes clear that just making scientific data available to the public through the media and the Internet is not enough. In addition, researchers and the medical profession also need to present their evidence in a compelling manner that engages parents and taps into parental concerns about their children's welfare and safety. Such an approach may seem to go against the fact-driven nature of science, but it may be necessary in order to use media outlets successfully to spread the message.

Part of the problem for the medical community in making a compelling case comes from the very success of vaccines. The mothers of this generation have not seen firsthand the devastation that the diseases their children are vaccinated against can cause. They have, however, become more and more aware of autism, especially as rates of diagnosis have skyrocketed in recent years. Given this knowledge differential, parents' risk assessment may be skewed against vaccines. As Arthur Caplan, a bioethicist at the University of Pennsylvania, points out, "one of the bitter ironies of vaccination is it carries with it the problems of its own success. . . . Many parents are not thinking about the risk side of disease because they don't see those diseases."<sup>195</sup> If the medical community wants to restore faith in vaccines in a post vaccine-autism myth world, it has to address this problem somehow, preferably before the problem solves itself through decreased vaccine rates and reoccurrences of these diseases.

One place to start may be to take more time to explain vaccines to parents, and more importantly, the dangers of the diseases those vaccines are meant to prevent. This kind of

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<sup>194</sup> *Frontline: The Vaccine War* (PBS television broadcast Apr. 27, 2010); video available at <http://www.pbs.org/wgbh/pages/frontline/vaccines/>, transcript available at <http://www.pbs.org/wgbh/pages/frontline/vaccines/etc/script.html>.

<sup>195</sup> *Id.*

dialogue may be especially important in an age where the Internet allows people to access medical information and self-diagnose, increasing their ability to participate in making medical decisions. One complaint some parents who are skeptical of vaccines have against the medical community is that their concerns are dismissed out of hand and may even anger health workers.<sup>196</sup> Such a response alienates parents and creates a distance between the patient and the physician. Instead of shutting down discussion before it can even begin, physicians should take the time to talk with their patients and address their concerns, even if the physicians believe those concerns are not based on legitimate science. In the information age, members of the health profession need to realize that they can no longer simply mandate a course of treatment and expect their patients to accept that mandate on the assumption that doctors know best. Instead, physicians have to take the extra step of demonstrating why they know best, using the opportunity to clear up any misconceptions patients may have about the prescribed treatment.

Another conversation that has to take place between the medical community and the public involves individual choice versus the public welfare. This is a discussion that is overdue in the wake of the vaccine-autism controversy. The problem is that, for many parents, vaccination is seen as a personal choice rather than something to be mandated by the government. For the government, though, vaccination plays a crucial role in maintaining a healthy citizenry. Specifically, vaccines, if effectively administered, lead to herd immunity. Herd immunity is an indirect benefit of vaccination that impedes the ability of a disease to spread. When the majority of the population is vaccinated, the virus cannot find suitable hosts, and may thus die out.<sup>197</sup> This is what happened with the smallpox virus. As the level of herd immunity increases (i.e., more

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<sup>196</sup> *Id.* (Interview with Jennifer Margulis, a parent who expresses skepticism towards vaccines, in which she relates how the nurse got angry when Margulis asked why her newborn daughter needed the hepatitis B vaccine).

<sup>197</sup> *See id.* (discussion between several interviewees, including Arthur Caplan and Dr. Paul Offit, about herd immunity and how vaccines are critical to maintaining such immunity).

people are vaccinated), the rate of transmission decreases.<sup>198</sup> This secondary benefit of vaccination may be particularly important for protecting vulnerable members of the population who, because of underlying health issues, age, or some other condition, cannot be vaccinated themselves.

From a public health perspective, then, it makes sense to vaccinate as many in the population as possible. For individual mothers, however, their children come first. And if they have any concerns about vaccines, which many do in the wake of the vaccine-autism controversy, they want to be able to opt out, regardless of what it means for society at large. This after-effect of the myth is much more difficult to address in a place like the United States, with its emphasis on individual freedom. Once again, the best starting place may be the physician's office, where parents can be educated on how vaccinations can indirectly help to protect the most vulnerable members of the population. If parents can be made to understand that their choices may help to protect other children, especially those who are too young to be vaccinated themselves, they may be more open to vaccination. This may be even more true if the discussion also includes information about the safety of vaccines, the difference between correlation and causation in the autism context, and the dangers presented by non-vaccination. Ultimately, by taking the time to speak with parents, to let parents give voice to their concerns, and to educate parents on both the risks of non-vaccination as well as the benefits of vaccination, physicians may be able to reclaim a place of prominence and expertise in the eyes of parents, in spite of the vast amounts of information available through the Internet. At the very least, parents may become more willing to turn to physicians for information, instead of just relying on Google results. If this were to occur, then the harmful consequences of the vaccine-autism myth may finally be mitigated. In addition,

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<sup>198</sup> See Peter G. Smith, *Concepts of Herd Protection and Immunity*, 2 *PROCEDIA VACCINOLOGY* 134, 134 (2010).

should other myths arise in the future, the medical community will be able to use the trust that it has built with the public to stop the propagation of those myths.

## **Conclusion**

Regardless of which side one falls on in the vaccine-autism controversy, the underlying concern is children's safety. For those who are skeptical of vaccines, they worry that getting children vaccinated may harm them by consigning them to a life of autism and its associated developmental and behavioral problems. For those who believe in vaccination, the worry is that unprotected children will be vulnerable to a host of potentially deadly diseases. It is this common concern over the welfare of children that must be emphasized in efforts to dispel the vaccine-autism myth. Parents want what is best for their children. The myth propagated by Wakefield has convinced many parents that what is best is not vaccination. By taking the time not only to show evidence rejecting the vaccine-autism myth, but also to show the risks of not vaccinating, the medical community may slowly rebuild faith in vaccines, putting the myth to rest. Such an outcome will truly be the best result for children: they will be kept safe from disease while resources will be re-devoted to finding the actual causes of autism.